

# EXHIBIT 4

EXHIBIT NO.

712A

The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health

**CONFIDENTIAL**

Division of Health Professions Licensure

239 Causeway Street, Suite 200

Boston, MA 02114

Office of Public Protection

(617) 973-0865 Fax (617) 973-0985 TTY (617) 973-0895

**INSPECTION REPORT**Docket No. or Staff Assignment No. ISP-738

Date of Inspection	<u>5/24/11</u>	Pharmacy Lic. No.	<u>DJ2848</u>	Expiration Date	<u>12/31/11</u>
Purpose of Inspection:	New Store <input type="checkbox"/>	Relocation <input type="checkbox"/>	Compliance <input checked="" type="checkbox"/>		
Corporation Name	<u>New England Compounding Pharmacy, Inc.</u>				
Pharmacy DBA Name	<u>New England Compounding Center</u>	Store No.			
Address	<u>697 Highland Street, Framingham, MA 01702</u>				
Telephone No.	<u>508-820-0606</u>	Fax No.	<u>888-820-0587</u>		
Manager of Record	<u>Benny J. Cohen</u>	Lic. No.	<u>PH21279</u>		
Name of RPH Completing Form			Lic. No.		
Pharmacy DEA Registration No. and Expiration Date	<u>BA5923819 10/31/2013</u>				
Pharmacy Hours	Daily <u>8A-5P</u>	Saturday <u>          </u>	Sunday <u>          </u>		
Practice Setting	Community Chain <input type="checkbox"/>	With Drive-thru Window <input type="checkbox"/>			
	Community Independent <input type="checkbox"/>	Specialty <input checked="" type="checkbox"/>	Long Term Care <input type="checkbox"/>		
<u>Compounding Sterile from Sterile</u>					
Daily Pharmacy Volume	Less than 100 <input type="checkbox"/>	100 to 500 <input type="checkbox"/>	Above 500 <input type="checkbox"/>		

100 orders 1 day shipped approximately

## PHARMACISTS

Name

License Number

CONFIDENTIAL

Name	License Number	License Status
1. ✓ Barry J. Cadden	PH 21239	Current
2. ✓ Glenn A. Chin	PH 21609	Current
3. ✓ Kathy S. Chin	PH 23360	Current
4. ✓ Joseph M. Eganosky	PH 233343	Current
5. ✓ Christopher Leary	PH 27442	Current
6. ✓ Alexander Stenants	PH 20114	Current
✓ George S. Stenants	PH 26669	Current
✓ George S. Stenants (Consistent)	PH 21096	Current

## PHARMACY INTERNS

Name

License Number

License Status

Name	License Number	License Status
1. ✓ Michael R. Jones	P 115588	Current
2.		
3.		
4.		
5.		
6.		

## PHARMACY TECHNICIANS

Name

License Number

Certification Status

License Status

Name	License Number	Certification Status	License Status
1. Lindsay J. Anthony	PT 8308	PTCB/NG	Current
2. ✓ Sharon P. Carter	PT 3787	PTCB/NG	Current
3. ✓ Belminah M. Carvalho	PT 3186	MA/NG	Current
4. ✓ Leticia E. Coltrane	PT 5724	PTCB/NG	Current
5. ✓ William Chi	PT 8696	PTCB/NG	Current
6. ✓ Joseph P. Connelly	PT 11766	PTCB/NG	Current

## OTHER PHARMACY STAFF including Trainees

Name

Position

Trainee Hours

Name	Position	Trainee Hours
1. ✓ O'way J. Finnegan	PT 6814	PTCB/NG Current
2. ✓ Cory B. Fitcher	PT 6856	PTCB/NG Current
3. ✓ Stephen D. Haynes	PT 10449	PTCB/NG Current
4. ✓ Stephen F. Lutz	PT 9376	PTCB/NG Current
5. ✓ Nicole M. Marshall	PT 10384	PTCB/NG Current
6. ✓ Annelle M. Robinson	PT 6519	PTCB/NG Current
✓ Ashlie D. Trukhan	PT 7990	PTCB/NG Current
✓ Derek M. Carvalho	PT 17982	PTCB/NG Current

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✓ = on staff 5/24/11 8847

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SECURITY - 247 CMR 6.02 and 21 CFR Section 1301.75(b)		YES	NO
<b>CONFIDENTIAL</b>			
ADEQUATE SECURITY SYSTEM		<input checked="" type="checkbox"/>	
EVIDENCE OF SECURITY CAMERAS	37 cameras	<input checked="" type="checkbox"/>	
SECURITY BARRIER SEPARATES PHARMACY DEPARTMENT		<input checked="" type="checkbox"/>	
PROCEDURE FOR ABSENCE OF PHARMACIST		N/A	
CONTROLLED SUBSTANCES ARE LOCKED IN A SECURE CABINET	CII + CIII - CE	<input checked="" type="checkbox"/>	
CONTROLLED SUBSTANCES ARE DISPERSED THROUGHOUT GENERAL INVENTORY		N/A	
LOSS OR THEFT OF CONTROLLED SUBSTANCES (DHA FORM 106) REPORTED TO THE BOARD		<input checked="" type="checkbox"/>	
SECURITY/ACCESS TO PHARMACY RESTRICTED TO AUTHORIZED PERSONNEL		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
COMMENTS 2-1/7 Security Monitoring			

LICENSURE/REGISTRATION STATUS OF PHARMACY STAFF		YES	NO
COPIES OF PHARMACIST LICENSES ARE POSTED AND CURRENT		<input checked="" type="checkbox"/>	
COPIES OF TECHNICIAN REGISTRATIONS ARE CURRENT AND AVAILABLE		<input checked="" type="checkbox"/>	
PROCEDURES IN PLACE TO MAINTAIN PATIENT CONFIDENTIALITY WITH REGARD TO DISCARDED PRESCRIPTION INFORMATION (e.g. SHREDDER)		<input checked="" type="checkbox"/>	
COMMENTS			

STANDARDS FOR PRESCRIPTION LABELING AND FORMAT M.G.L. c. 94C, § 21 and 105 CMR 721.000		YES	NO
PHARMACIST INITIALS ON LABEL AND SERIAL NO. OF RX		<input checked="" type="checkbox"/>	
"BEYOND USE" DATE IS SHOWN ON LABEL		<input checked="" type="checkbox"/>	
INVENTORY LABELED WITH BRAND, OR GENERIC NAME AND MANUFACTURER, STRENGTH, LOT NUMBER, EXPIRATION DATE, OR INTERNAL CONTROL NUMBER WHICH REFERENCES MANUFACTURER AND LOT NUMBER USED		<input checked="" type="checkbox"/>	
LABEL COMPLIANT WITH INTERCHANGE		<input checked="" type="checkbox"/>	
PRESCRIPTION CONTAINS ALL REQUIRED INFORMATION		<input checked="" type="checkbox"/>	
ORALLY COMMUNICATED PRESCRIPTIONS ARE IMMEDIATELY DOCUMENTED		<input checked="" type="checkbox"/>	
COMMENTS Labels compliant with nature of practice			

OUTDATED ITEMS/RETURN TO STOCK		YES	NO
QUARANTINE AREA FOR CONTROLLED SUBSTANCE RECALLS OR EXPIRED PRODUCT SEGREGATED FROM CURRENT INVENTORY		<input checked="" type="checkbox"/>	
COMMENTS General Chemical / Clean Ventures Every 6 months process			

CONTROLLED SUBSTANCE RECORDS ELECTRONICALLY TRANSMITTED PRESCRIPTIONS PMP REPORTING REQUIREMENTS 247 CMR 5.00, 105 CMR 700, 21 CFR Part 1300 - 1308		CONFIDENTIAL	YES	NO
PRESCRIPTION RECORDS ARE ON SITE AND READILY RETRIEVABLE FOR 2 YEARS				
THE LAST BIENNIAL INVENTORY COMPLETED <u>10/5/17</u> AND SHOWS BEFORE OPENING OR AFTER CLOSING				
POWER OF ATTORNEY GRANTED TO PERSONS SIGNING DEA FORM 222 AND READILY AVAILABLE				
POWER OF ATTORNEY FORM FOR DEA FORM 222 GRANTED TO: <u>N/A</u>				
COMPLETE RETURN AND DESTRUCTION RECORDS OF CONTROLLED SUBSTANCES READILY AVAILABLE				
EMERGENCY C-II PRESCRIPTION RECORDS ARE COMPLETE AND PROPERLY FILED <u>N/A</u>				
SCHEDULE II PRESCRIPTION DATA (PMP) TRANSMITTED BY COMPUTER ON TIME (247 CMR 5.04)				
CENTRAL RECORD KEEPING AUTHORITY FILED WITH DEA				
DEA ORDER FORMS FILLED OUT COMPLETELY, INCLUDING DATE AND QUANTITY RECEIVED				
CII ORDER FORMS RECONCILED SATISFACTORILY				
CIII-V INVOICES RECONCILED SATISFACTORILY				
DAILY REPORTS ARE AVAILABLE, VERIFIED, AND SIGNED BY ALL PHARMACISTS INVOLVED <u>✓</u>				
CII PERPETUAL INVENTORY RECONCILED WITHIN 10 DAYS <u>N/A</u>				
COMMENTS <u>* Registrant is owner</u> <u>** Each Simulation sheet signed by RPS.</u>				

TRANSFER OF PRESCRIPTIONS - 247 CMR 9.02		YES	NO
CORRECT TRANSFER RECORDS ARE MAINTAINED AND READILY AVAILABLE			
DAILY REPORTS ARE AVAILABLE, VERIFIED AND SIGNED BY ALL PHARMACISTS INVOLVED <u>✓</u>			
PATIENT PROFILES ARE MAINTAINED <u>N/A</u>			
COMMENTS <u>* Each Simulation sheet signed by RPS.</u>			

EQUIPMENT and REFERENCE SOURCES - 247 CMR 6.01		YES	NO
COMPUTER SOFTWARE NAME: <u>DK Software</u>			
TORSION BALANCE AND WEIGHTS: <u>SEALED DATE 1/2/11 (A1150000)</u>			
COMPOUNDING LOG MAINTAINED			
APPROPRIATELY SIZED SAFETY CONTAINERS AVAILABLE AND USED ROUTINELY (16 CFR 1700)			
CURRENT COPY OR E-VERSION OF APPROPRIATE COMPENDIA REFERENCE AVAILABLE			
CURRENT COPY OR E-VERSION OF MA BOARD OF PHARMACY REGULATIONS AVAILABLE			
CURRENT COPY OR E-VERSION OF MA LIST OF INTERCHANGEABLE DRUGS AVAILABLE			

CONTINUOUS QUALITY IMPROVEMENT (CQI) PROGRAM QUALITY RELATED EVENTS (QRE) - 247 CMR 15.00		YES	NO
CURRENT COPY OR E-VERSION OF CQI PROGRAM AVAILABLE		<input checked="" type="checkbox"/>	<input type="checkbox"/>
QRE RECORDS (2 YEARS) ARE MAINTAINED IN AN ORDERLY MANNER AND FILED BY DATE		<input checked="" type="checkbox"/>	<input type="checkbox"/>
PHARMACY PROVIDES PERSONNEL WITH ONGOING CQI EDUCATION AT LEAST ANNUALLY		<input checked="" type="checkbox"/>	<input type="checkbox"/>
POLICY AND PROCEDURES ON SITE RELATED TO THE HANDLING OF MEDICATION ERRORS		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COMMENTS			

PATIENT COUNSELING M.G.L. c. 94C, § 21A and 247 CMR 6.01 and 9.07		YES	NO
PATIENT COUNSELING SIGNS (11" x 14") POSTED (INCLUDING DRIVE THRU)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
ADEQUATE OFFER TO COUNSEL MADE AND DOCUMENTED		<input checked="" type="checkbox"/>	<input type="checkbox"/>
DESIGNATED CONFIDENTIAL PATIENT CONSULTATION AREA		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COUNSELING AREA ASSURES PRIVACY AND CONFIDENTIALITY		<input checked="" type="checkbox"/>	<input type="checkbox"/>
PROSPECTIVE DUR ON NEW PRESCRIPTIONS CONDUCTED		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COMMENTS <i>2-3 patients counsel Cura to Center</i>			

SANITATION - 247 CMR 6.02 and 9.01		YES	NO
PHARMACY (INCLUDING SINK, REFRIGERATOR, COUNTING TRAYS, AND AUTOMATED DISPENSING MACHINES) KEPT CLEAN AND ORGANIZED		<input checked="" type="checkbox"/>	<input type="checkbox"/>
REFRIGERATOR MAINTAINED WITHIN RANGE COMPLIANT WITH STORAGE OF DRUGS REQUIRING REFRIDGERATION TEMPERATURE		<input checked="" type="checkbox"/>	<input type="checkbox"/>
ROOM TEMPERATURE IS 59 - 77 DEGREES F.		<input checked="" type="checkbox"/>	<input type="checkbox"/>
PRESCRIPTION COUNTER IS USED ONLY FOR PREPARING PRESCRIPTIONS		<input checked="" type="checkbox"/>	<input type="checkbox"/>
PRESCRIPTION DEPARTMENT HAS SPACE ADEQUATE FOR THE SIZE AND SCOPE OF PHARMACEUTICAL SERVICES PROVIDED BY THE PHARMACY		<input checked="" type="checkbox"/>	<input type="checkbox"/>
SUFFICIENT EQUIPMENT TO COMPOUND AND DISPENSE PRESCRIPTIONS		<input checked="" type="checkbox"/>	<input type="checkbox"/>
SINK HAS HOT AND COLD RUNNING WATER		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COMMENTS <i>* Refrigerators in non sterile &amp; sterile areas. Temperatures that could be maintained in acceptable range (no freezer) kept in place on all units.</i>			

CENTRAL INTRAVENOUS ADMIXTURE SERVICE (CIVAS) 247 CMR 6.01(5)(c)		YES	NO
CLEAN ROOM - MINIMUM OF 72 SQUARE FEET		<input checked="" type="checkbox"/>	<input type="checkbox"/>
CLEAN ROOM ADJACENT TO PRESCRIPTION DEPARTMENT		<input checked="" type="checkbox"/>	<input type="checkbox"/>
HOODS:	HORIZONTAL <i>Two BSCs Confined Clean rooms</i> VERTICAL <i>hoods &amp; Glove Boxes</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CIVAS APPROVAL LETTER FROM BOARD MAINTAINED ON PREMISES <i>Posted in Clean Room</i>		<input checked="" type="checkbox"/>	<input type="checkbox"/>

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CENTRAL INTRAVENOUS ADMIXTURE SERVICE (CIVAS)		YES	NO
247 CMR 6.01(5)(c) continued		<b>CONFIDENTIAL</b>	
WRITTEN QUALITY ASSURANCE GUIDELINES MAINTAINED ON PREMISES		<input checked="" type="checkbox"/>	<input type="checkbox"/>
TRAINING IN STERILE PROCEDURE AVAILABLE AND CONDUCTED		<input checked="" type="checkbox"/>	<input type="checkbox"/>
ADEQUATE REFERENCE STANDARDS		<input checked="" type="checkbox"/>	<input type="checkbox"/>
ANNUAL CERTIFICATION OF LAMINAR HOOD AND CLEAN ROOM CONDUCTED		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COMMENTS		<i>S.O.P.'s on file</i> <i>All staff trained</i> <i>Aseptic training checklist</i>	

*Dedicated  
QA person*

TECHNICIANS - 247 CMR 8.00		YES	NO
PHARMACY TECHNICIANS OPERATE WITHIN THE SCOPE OF LAW AND REGULATIONS		<input checked="" type="checkbox"/>	<input type="checkbox"/>
TECHNICIANS WEAR NAME TAGS EASILY READABLE WITH TITLE AND NAME		<input checked="" type="checkbox"/>	<input type="checkbox"/>
TECHNICIANS FOLLOW DUTIES AS SPECIFIED IN WRITTEN POLICIES AND PROCEDURES		<input checked="" type="checkbox"/>	<input type="checkbox"/>
TECHNICIANS ARE SUPERVISED BY A PHARMACIST		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COMMENTS			

VACCINATION/CPR - 105 CMR 700.004		YES	NO
PHARMACIST ADMINISTERING VACCINES TO PERSONS 18 YEARS OF AGE OR OLDER		<input checked="" type="checkbox"/>	<input type="checkbox"/>
CURRENT CPR CARD		<input checked="" type="checkbox"/>	<input type="checkbox"/>
ADMINISTRATION IS CONDUCTED PURSUANT TO THE ORDER OF A PRACTITIONER		<input checked="" type="checkbox"/>	<input type="checkbox"/>
DOCUMENTATION OF ACCREDITED TRAINING		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COMMENTS			

MANAGER OF RECORD (MOR) - 247 CMR 6.07		YES	NO
MOR CAN DEMONSTRATE IMPLEMENTATION OF A CQI PROGRAM		<input checked="" type="checkbox"/>	<input type="checkbox"/>
MOR HAS COPIES OF CONFIDENTIALITY STATEMENTS FROM EACH EMPLOYEE		<input checked="" type="checkbox"/>	<input type="checkbox"/>
MOR IS RESPONSIBLE FOR ESTABLISHING AND MONITORING POLICIES AND PROCEDURES:		<input checked="" type="checkbox"/>	<input type="checkbox"/>
(a) STAFF TRAINING ONGOING		<input checked="" type="checkbox"/>	<input type="checkbox"/>
(b) TECHNICIAN MANUAL ON PREMISES		<input checked="" type="checkbox"/>	<input type="checkbox"/>
(c) RATIO PHARMACIST TO SUPPORT PERSONNEL		<input checked="" type="checkbox"/>	<input type="checkbox"/>
COMMENTS		<i>Sharon Cantan - CPhT</i> <i>Responsible for CQI</i> <i>(both patient - level &amp; business components)</i>	

WHOLESALE DISTRIBUTOR INFORMATION		
NAME(S) OF SUPPLIERS		
<b>CONFIDENTIAL</b>		
<i>Spokane</i>		
GENERAL		
PHARMACY GRANTED ANY WAIVERS BY THE BOARD OR DEA TO ANY LAWS OR RULES	YES	NO
PHARMACY SHARES A REAL-TIME COMMON DATABASE WITH OTHER PHARMACIES	✓	✓
PHARMACY UTILIZES THE SERVICES OF A CENTRAL FILL PHARMACY		✓
VERIFYING PHARMACIST(S) IS DOCUMENTED		✓
PHARMACY PERSONNEL WEAR APPROPRIATE NAME TAGS	✓	
PROCEDURE TO ENSURE ALL WHO WORK IN THE PHARMACY ARE APPROPRIATELY AND CURRENTLY REGISTERED OR LICENSED AND TRAINED TO PERFORM THEIR DUTIES	✓	
SIGN(S) POSTED REGARDING PHARMACY HOURS OF OPERATION	✓	
COMMENTS		
<i>* Scope of practice limited          Prepare this note          State Injectables          No TPM currently</i>		

I have participated in an inspection and have reviewed the Inspection Report with the Investigator.

Print Name BARRY J. COHEN Signature Barry J. Cohen  
 Title Pharmacy Director License No. MA21239  
 Investigator W. R. F. J. Date 5/24/11

\* Not - state lab - creams, ointments, ophthalmics  
 \* Service multiple states, licensed in 48 states  
 & 2 that don't require licensing